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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/418,536	10/14/1999	DANIEL J. POWERS	10981567-1	9017

24737 7590 11/03/2004

PHILIPS INTELLECTUAL PROPERTY & STANDARDS
P.O. BOX 3001
BRIARCLIFF MANOR, NY 10510

EXAMINER	
OROPEZA, FRANCES P	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 11/03/2004

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/418,536
Filing Date: October 14, 1999
Appellant(s): POWERS ET AL.

W. Brinton Yorks, Jr.
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed March 19, 2004 and July 19, 2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief but it is incorrect. According the to U.S. Patent and Trademark Office records, the real party of interest is Koninklijke Philips Electronics N.V. in Eindhoven, Netherlands.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences that will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 1-16 and 18 stand or fall together. Applicant's brief includes a statement that claims 19-28 stand or fall together.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct except for claim 20. Claim 20 contains substantial errors as presented in the Appendix to the brief and in the Appendix to the supplemental brief. Accordingly, claim 20 is correctly written in the Appendix to the Examiner's Answer.

(9) Prior Art of Record

6,292,692	SKELTON et al.	9-2001
6,141,584	ROCKWELL et al.	10-2000
5,879,374	POWERS et al.	3-1999

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

I. Rejection of claims 1-12, 14 and 18-28 under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Skelton et al. (US 6,292,692)

Claims 1-12, 14 and 18-28 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Skelton et al. (US 6,292,692).

Skelton et al. disclose a defibrillation device operated under pass control enabling the device to be reconfigured for use by individuals with different levels of training (col. 4 @ 21-24; col. 5 @ 26-46). The treatment device (10) includes a printer (60), a display (24), keys (68) for menu selection, and keys (70) for pass-code entry and feature setting (col. 10 @ 15-52). Audio recording is disclosed (col. 9 @ 54-56; col. 7 @ 66 – col. 8 @ 4). The outputs of various treatment device modules can be graphically displayed (col. 9 @ 64-67). A treatment summary is created that records pace markers, time indications and key events (col. 7 @ 26-35). Access to the recorded log can be restricted (col. 10 @ 53 – col. 11 @ 27).

Skelton et al. disclose:

1) deployment of a defibrillator (col. 3 @ 40-42),

2) monitoring of the ECG data (col. 3 @ 25-29; col. 5 @ 37-39),

3) recording the ECG data and display same in an incident review mode on the same screen. The pulse data (col. 4 @ 12-16) including the waveform (col. 8 @ 24-26) is provided to supplement the defibrillation therapy. The data is recorded for review (col. 6 @ 15-25); accumulated ECG data can be reviewed (col. 12 @ 13-22). The data displayed in figure 4 reference number 98 (a) is an ECG trace. The means to control which waveform is displayed is disclosed in figure 10, reference number 162. The ECG waveform displayed on the screen is controlled as shown in figure 10 using the buttons (70) associated with the "Trace Menu" window (162). The waveform could be the current waveform or a historical waveform (col. 6 @ 15-25;

col. 12 @ 13-22), and

4) displaying recorded ECG data off-line by way of the printer strip (col. 10 @ 64-67).

As to displaying the recorded ECG data on the defibrillation screen of the defibrillator while the patient is being monitored, Skelton et al. teach patient monitoring and data display as two separate activities; the data display does not limit the patient monitoring. Skelton et al. monitor the pulse data/ ECG/ pulse waveform of the patient (col. 4 @ 12-16 and 63-65; col. 5 @ 37-39; col. 8 @ 24-26). The monitoring is ongoing/ continuous (col. 3 @ 24-29; col. 4 @ 63-65) enabling the user to review any of the historical data accumulated by the device (col. 12 @ 14-16) and/ or enabling the ECG analysis module to send a permissive signal to the SAED defibrillator medical treatment module so the user can discharge the defibrillation capacitors treating the patient(col. 5 @ 49-55).

As to displaying previously recorded and currently monitored information simultaneously on the screen, ECG data is monitored (col. 5 @ 37-39; col. 8 @ 24-26) and currently monitored ECG data is displayed on the screen (col. 5 @ 37-39; col. 9 @ 64-67). The monitoring is ongoing/ continuous (col. 3 @ 24-29; col. 4 @ 63-65). Recorded data is made available for review (col. 6 @ 15-25)/ accumulated ECG data can be reviewed (col. 12 @ 13-16), hence enabling the user to review any of the historical data accumulated by the device. Based on operator selection, up to three waveforms can be displayed on the screen (figure 4 (98 a-c); col. 12 @ 10-29), hence the two waveforms displayable simultaneously on the screen are read as the previously recorded ECG data and the currently monitored EGC data.

As to recorded ECG data being displayed on the display for the user, the medical treatment device (10) includes treatment modules (12-16) (col. 3 @ 29-33). The device (10) enables medical treatment modules, one module being ECG monitoring (col. 5 @ 37-39). The data monitoring operation includes recording the data, the data used at the time of treatment or recorded for later use (col. 2 @ 3-10; col. 13 @ 57-63). The recorded data is made available to the user on the display (24) (figure 3). The recorded output of the ECG module is graphically displayed (figure 4 - 98 a) (col. 9 @ 64-67). Accummulated data, including recorded ECG data, is displayed (col. 12 @ 10-16).

As to the recorded ECG data being displayed simultaneously with currently monitored information, the display allows graphic display of three data traces (figure 4). The traces shown on the screen can be altered (figure 8; col. 12 @ 13-22; col. 11 @ 28-30 ; col. 13 @ 44-48). As to the claimed invention, Skelton et al. is read as teaching the display of two traces (col. 12 @ 16-22), one is the currently monitored ECG (col. 13 @ 57-61) and the second is recorded ECG data (col. 12 @ 13-22).

In the alternative, Skelton et al. teach levels of treatment are made available to caregivers based on their skill level (col. 2 @ 5-10; col. 4 @ 21-24; col. 5 @ 26-45), the levels of treatment controlled by passcode (col. 5 @ 39-45) that enable authorized caregivers to display the information needed to provide patient care (col. 9 @ 64 – col. 10 @ 6; col. 10 @ 11 – col. 11 @ 31; col. 12 @ 10-28;

col. 13 @ 44-48 and 57-61; col. 6 @ 18-27). Skelton et al. teach simultaneously displaying previously recorded and currently monitored information on the screen. ECG data is monitored (col. 5 @ 37-39; col. 8 @ 24-26), the monitoring being ongoing/continuous (col. 3 @ 24-29; col. 4 @ 63-65). Currently monitored ECG data is displayed on the screen (col. 5 @ 37-39; col. 9 @ 64-67). Recorded data is made available for review (col. 6 @ 15-25)/ accumulated ECG data can be reviewed (col. 12 @ 13-16), hence enabling the caregiver to review historical data accumulated by the device. Based on caregiver selection, up to three waveforms can be displayed on the screen (figure 4 (98 a-c); col. 12 @ 10-29), hence given the caregiver has appropriate passcode access, it is an obvious teaching to display two waveforms simultaneously on the screen, the previously recorded ECG data and the currently monitored EGC data.

II. Rejection of claims 4 and 12 under 35 U.S.C. 103(a) as being unpatentable over Skelton et al. (US 6,292,692) in view of Rockwell et al. (US 6,141,584), or in the alternative, as obvious over Skelton et al. (US 6,292,692) in view of Rockwell et al. (US 6,141,584)

Claims 4 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skelton et al. (US 6,292,692) in view of Rockwell et al. (US 6,141,584), or in the alternative, as obvious over Skelton et al. (US 6,292,692) in view of Rockwell et al. (US 6,141,584).

As discussed in 10) Grounds of rejection, Section I. of this Examiner's Answer, Skelton et al. disclose the claimed invention except for the replay step occurring automatically without user activation (claim 4) and when the patient is disconnected from the device (claim 12).

Rockwell et al. disclose a defibrillator and communication system and teach that an event summary can be generated automatically at handoff (col. 9 @ 36-38; col. 12 @ 12-16). It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the replay step occurring automatically without user activation and when the patient is disconnected from device/ ECG is displayable offline in the Skelton et al. device in order to enable the care givers to review the data critical times, such as movement to a new machine or situation, to ensure patient care is progressing in an optimum fashion, and to ensure key treatments and historical events are properly noted by the medical personnel so that proper care and follow-up treatment occurs (col. 12 @ 20-24).

III. Rejection of Claims 13 and 15-16 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Skelton et al. (US 6,292,692) in view of Powers et al. (US 5,879,374), or in the alternative, as obvious over Skelton et al. (US 6,29,2692) in view of Powers et al. (US 5,879,374)

Claims 13 and 15-16 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Skelton et al. (US 6,292,692) in view of Powers et al. (US 5,879,374), or in the alternative, as obvious over Skelton et al. (US 6,292,692) in view of Powers et al. (US 5,879,374).

As discussed in 10) Grounds of rejection, Section I. of this Examiner's Answer, Skelton et al. disclose the claimed invention except:

- activation of the incident review mode in response to insertion of the battery, and

- offering the replay option when the defibrillator is turned off or when the battery is inserted.

Powers et al. disclose an external defibrillator with automatic self-testing prior to use. Powers et al. teach that it is known to use the insertion of a battery as the trigger to automatically generate a test signal. The test signal initiates a plurality of preset self-tests or activities within the defibrillator (col. 2 @ 57 – col. 3 @ 10). It is an obvious design choice that the insertion of the battery could activate the incident review mode and/or initiate an offer to replay the recorded data. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the battery insertion to trigger the activation of the incident review mode and/ or the replaying of the stored data in the Skelton et al. device in order to gain quicker access to the incident review mode and/or the stored data.

Powers et al. teach that it is known use a gate array as a system monitor in the scenario of low power. Low power is viewed as equivalent to an impending system shutdown, hence it is an obvious design choice to have the ASIC (application specific integrated circuit) perform various tasks at the low power or shutdown point including offering to replay the stored data. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the offer to replay the stored data at shutdown in the Skelton et al. device in order to keep the rescue personnel advised of the events to date in the rescue operation.

(11) Response to Argument

Response to Arguments with respect to Section I. of the Grounds of Rejection - Rejection of claims 1-12, 14 and 18-28 under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Skelton et al. (US 6,292,692)

The Appellants establish six arguments in the Appeal Brief and further argued one of the arguments in the Supplemental Appeal Brief.

1) On page 7 of the Appeal Brief, the Appellants' state the medical treatment device of Figure 4 can show up to three graphic traces ((98 a-c); col. 12 @ 10-26; col. 9 @ 64-67), and assert the traces could be an ECG trace, an oxygen level trace, and a respiration trace (col. 9 @ 64-67), but not the current ECG waveform and a historical ECG waveform. The Examiner disagrees.

The three traces shown on the display (24) are defined by the key press sequence associated with figure 10 (col. 9 @ 64-67; col. 12 @ 14-28), the source of the data for the traces recognized to be the medical treatment modules. The user could choose one trace to be the current ECG data associated with the ECG monitor module (figure 4 – 98a; col. 5 @ 38; col. 9 @ 66; col. 12 @ 16). The second trace could be: historical ECG data located in the optional associated data storage area of the ECG monitoring module (col. 5 @ 38; col. 12 @ 10-14), or the historical ECG data associated with the ECG patient treatment module
(col. 13 @ 44-48).

The discussion associated with figure 8 and the citation of column 12 serves as the basis for some of the teachings above. While figure 8 discusses the respiratory

monitoring module, it is understood the respiratory module was select to demonstrate the teaching, and the teachings apply to all the monitoring modules including the ECG module.

2) On page 7 of the Appeal Brief the Appellants assert "historical data, that is, recorded physiological data or user inputs are record by the use of log functions and devices on the Skelton et al. device" (col. 6 @ 18-27 and 59-63). The Appellants assert Skelton et al. display this data by means of its chart or strip printer (Figure 6; col. 9 @ 31-37). The Appellants' assert the historical data is reviewed only by means of a chart of strip printer (62) (col. 9 @ 31-37) and there is no the display of historical data on the screen of the Skelton et al. device. The Examiner disagrees.

The historical data is recorded by log function and/or recording devices (col. 5 @ 35-39; col. 6 @ 10-24 and 59-63) and can be reviewed using a printer strip chart (Figure 7) according to the schematic diagram of Figure 6 (col. 10 @ 53 – col. 11 @ 10). The historical data can also be reviewed on the display (Figure 4 – 24) using the medical treatment display module and the ECG patient treatment module, where the ECG related treatment data recorded in the module is displayed on the display (24) using the medical treatment display module (col. 13 @ 44-48).

3) On page 8 of the Appeal Brief, the Appellants assert a distinction between accumulated data and recorded (stored) data. The Appellants assert "accumulated data" at "the bottom of column 9" (assumed to be column 13, line 56 +) is data currently

acquired from sensors, hence not recorded. Recorded (stored) data is asserted to be "logged" data. Starting on page 5 of the Supplement Appeal Brief, the Appellants continues this argument asserting the citations in column 13, 12 and 6 do not teach the display of currently monitored data, the display of recorded data, and data made available for review respectively because the display of "accumulated data" or non-stored data is not the display of historical ECG data. The Examiner disagrees.

The Skelton et al. medical treatment device is a complex multi-level device that can be configured with various functionality by the supervisor (col. 4 @ 21-29; col. 6 @ 34-37) and this functionality controlled by passcode entry (abstract; col. 5 @ 20-25). The recorded data can be group into two basis areas, recorded/ logged/ charted user input data (col. 6 @ 59-63; col. 7 @ 23-40) and physiological data (col. 4 @ 12-16) . For both user input data and physiological data, the supervisor establishes what data is recorded, how it is configured, how it is disseminated and who has what privileges relative to data manipulation and storage (col. 6 @ 35-37; col. 4 @ 63 – col. 25; col. 13 @ 55-67).

The notion of "accumulated data" is a wonderful example of the complexity of the system. The significance of "accumulated data" being stored or not, is that the user has the choice to manipulate the data in this fashion (col. 13 @ 55-67). The Appellant takes the teaching of "accumulated data" to assert that only accumulated or non-stored data is displayed on the display (24) based on the citation at column 12 @ 16. The Examiner disagrees. While accumulated data can be displayed on the display (24)

(col. 12 @ 16), any output of the various medical treatment device modules can be graphically displayed, as indicated by waveforms 98a-98c appearing on the display (24) in Figure 4 (col. 9 @ 64-67), hence since both current and historical data are associated with the medical treatment modules as discussed in the first paragraph of Section 11, both current and historical ECG data can be simultaneously displayed on the display.

It is recognized the stored data can be stored by the user (the data being recorded/ logged/ charted user input data and/ or physiological data) (col. 6 @ 23-27 and 59-63; col. 7 @ 23-40) or can be automatically stored according to the device programming by the Supervisor (the data being recorded/ logged/ charted user input data and/ or physiological data) (col. 5 @ 13-25; col. 13 @ 55-57), hence one way or the other historical data is available for display.

It is clear the historical ECG data can be displayed on the device based on the following teachings:

1) "it is appropriate to limit data output...even though the date is stored within the medical treatment device and is not displayed or otherwise outputted" (understood to be the strip chart printer) "at the scene of the emergency" (col. 5 @ 23-27); and

2) The outputs of various medical device treatment modules is displayed, as indicated by waveforms 98a-98c appearing on display (24) (col. 9 @ 64-67) in combination with the teaching a trace on the display could be: historical ECG data located in the optional associated data storage area of the ECG monitoring module (col. 5 @ 38; col. 12 @ 10-14), or the historical ECG data associated with the ECG patient treatment module (col. 13 @ 44-48).

4) On page 9 of the Appeal Brief, the Appellants assert Skelton et al. do not have the ability to simultaneously display previously recorded and currently monitored ECG data on the screen of the Skelton et al. device. The Examiner disagrees.

The previously recorded and currently monitored ECG data are displayed on the screen as discussed in Section 11 – (1). The three traces shown on the display (24) are defined by the key press sequence associated with figure 10 (col. 9 @ 64-67; col. 12 @ 14-28), the source of the data for the traces recognized to be the medical treatment modules. The user could choose one trace to be the current ECG data coming from the sensor associated with the ECG monitor module (figure 4 – 98a; col. 5 @ 38; col. 9 @ 66; col. 12 @ 16). The second trace could be: historical ECG data located in the optional associated data storage area of the ECG monitoring module (col. 5 @ 38; col. 12 @ 10-14), or the historical ECG data associated with the ECG patient treatment module (col. 13 @ 44-48). The device transfers data from the modules over bus 28 to the microprocessor and displayed on the screen (24) (figure 1; col. 3 @ 57-65), hence the device is able to display previously recorded and currently monitored ECG data on the screen of the Skelton et al. device.

5) On page 9 of the Appeal Brief, the Appellants assert "There is no ability in Skelton et al. of the ability to display previously recorded ECG data on the device screen while the patient continues to be monitored for defibrillation". The Examiner disagrees.

As to displaying previously recorded ECG data on the screen, the three traces shown on the display (Figure 4 - 24) are defined by the key press sequence associated with figure 10 (col. 9 @ 64-67; col. 12 @ 14-28), the source of the data for the traces recognized to be the medical treatment modules. One trace could be: historical ECG data located in the optional associated data storage area of the ECG monitoring module (col. 5 @ 38; col. 12 @ 10-14), or the historical ECG data associated with the ECG patient treatment module (col. 13 @ 44-48).

As to "monitoring for defibrillation", the expert ECG analysis medical treatment module (col. 5 @ 38-39 and 49-60) is used in conjunction with the Basic defibrillation modules (34, 36, 38) to give a permissive signal for defibrillation, and is active without regard to the data being displayed on the device screen, hence the monitoring is ongoing and continuous when there is a supervisor programmed option for defibrillation using the Basic defibrillation control modules (34-36) (col. 5 @ 6-9).

6) On page 9 the Appeal Brief and as relate to claim 19, the Appellants assert neither Skelton et al. nor Rockwell et al. show or suggest the simultaneous display of retrieved incident data on the defibrillator screen and the current patient monitoring while the patient is being monitored. The Examiner disagrees.

As to data display, this claim relates to any recorded data and current monitoring data, not just ECG data. As discussed in Section 11 – (1) of this answer the three traces shown on the display (24) are defined by the key press sequence associated with figure 10 (col. 9 @ 64-67; col. 12 @ 14-28), the source of the data for the traces

recognized to be the medical treatment modules. The user could choose one trace to be the current respiratory data coming from the sensor associated with the respiration module (figure 4 – 98a; col. 11 @ 33-34; col. 9 @ 66; col. 12 @ 16). The second trace could be: historical ECG data located in the optional associated data storage area of the ECG monitoring module (col. 5 @ 38; col. 12 @ 10-14), or the historical ECG data associated with the ECG patient treatment module (col. 13 @ 44-48).

As to the patient being monitored, as previous discussed the expert ECG analysis medical treatment module (col. 5 @ 38-39 and 49-60) is used in conjunction with the Basic defibrillation modules (34, 36, 38) to give a permissive signal for defibrillation, and is active with out regard to the data being displayed on the device screen, hence the monitoring is ongoing and continuous when there is an supervisor programmed option for defibrillation using the Basic defibrillation control modules (34-36) (col. 5 @ 6-9).

Response to Arguments with respect to Section II. of the Grounds of Rejection - Rejection of claims 4 and 12 under 35 U.S.C. 103(a) as being unpatentable over Skelton et al. (US 6,292,692) in view of Rockwell et al. (US 6,141,584), or in the alternative, as obvious over Skelton et al. (US 6,292,692) in view of Rockwell et al. (US 6,141,584)

The Appellant argue Rockwell et al. do not teach "that which is missing from Skelton et al.". Based on the rejection of record and the discussion in Section (11), Skelton et al. teach and are able to simultaneously display previously recorded and currently monitored ECG data on the screen of the medical treatment device, hence "nothing is missing from Skelton et al.". It is noted Rockwell et al. was incorporated in

the rejection to teach the replaying step occurring automatically without user activation and when the patient is disconnected from the device.

Response to Arguments with respect to Section III. of the Grounds of Rejection - Rejection of Claims 13 and 15-16 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Skelton et al. (US 6,292,692) in view of Powers et al. (US 5,879,374), or in the alternative, as obvious over Skelton et al. (US 6,29,2692) in view of Powers et al. (US 5,879,374)

The Appellants argue Powers et al. do not show or suggest the ability to simultaneously display previously recorded and currently monitored ECG data on a screen of an external defibrillator. Based on the rejection of record and discussion in Section 11), Skelton et al. teach and are able to simultaneously display previously recorded and currently monitored ECG data on the screen of the medical treatment device. It is noted Powers et al. was incorporated in the rejection to teach activation of the incident review mode in response to insertion of the battery, and offering the replay option when the defibrillator is turned off or when the battery is inserted.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

France P. Oropeza
October 20, 2004

Conferees
Angela D. Sykes

ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

Jeffrey R. Jastrzab

JEFFREY R. JASTRZAB
PRIMARY EXAMINER

IP ADMINISTRATION
LEGAL DEPARTMENT 20BN
HEWLETT PACKARD COMPANY
P O BOX 10301
PALO ALTO, CA 94303-0890

APPENDIX: THE CLAIMS ON APPEAL

20. The external defibrillator of claims 19 wherein the memory is selected from the group consisting of removable memory and integral memory.